UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,950	11/16/2005	Thomas Herget	DFMP-P01-480	1016

28120 7590 09/13/2007

ROPES & GRAY LLP
PATENT DOCKETING 39/41
ONE INTERNATIONAL PLACE
BOSTON, MA 02110-2624

EXAMINER	
THOMAS, TIMOTHY P	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
09/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,950	HERGET ET AL.	
	Examiner	Art Unit	
	Timothy P. Thomas	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20,23,27-35,42,43 and 46-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20,23,27-35,42,43 and 46-56* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Acknowledgment is made of the preliminary amendments to the claims, filed 5/2/2006. Claims 21-22, 24-26, 36-41 and 44-45 are canceled. Claims 1-20, 23, 27-35, 42-43 and 46-56 are pending.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-8, 19-20, 51 (all in part), drawn to a composition comprising selenium or selenium salts.

Group II, claim(s) 1-8, 19-20, 51 (all in part), drawn to a compostion comprising Vitamin D3.

Group III, claim(s) 1-8, 19-20, 51 (all in part), drawn to a compostion comprising all trans retinoic acid, a derivative thereof or 4-HPR.

Group IV, claim(s) 1-8, 19-20, 51 (all in part), drawn to a compostion comprising a naphthalene derivative TTNPB, AM-580 or AHPN.

Group V, claim(s) 9-18, 23, 27-35, 52-56 (all in part), drawn to a method of regulating the production of Hepatitis C Virus (HCV) and/or preventing and/or treating HCV infection comprising administration of selenium or selenium salts.

Group VI, claim(s) 9-18, 23, 27-35, 52-56 (all in part), drawn to a method of regulating the production of Hepatitis C Virus (HCV) and/or preventing and/or treating HCV infection comprising administration of Vitamin D3.

Group VII, claim(s) 9-18, 23, 27-35, 52-56 (all in part), drawn to a method of regulating the production of Hepatitis C Virus (HCV) and/or preventing and/or treating HCV infection comprising administration of all trans retinoic acid, a derivative thereof or 4-HPR.

Group VIII, claim(s) 9-18, 23, 27-35, 52-56 (all in part), drawn to a method of regulating the production of Hepatitis C Virus (HCV) and/or preventing and/or treating HCV infection comprising administration of a naphthalene derivative TTNPB, AM-580 or AHPN.

Group IX, claim(s) 42-43, 46-50 (all in part), drawn to a method for regulating the expression or activity of the human cellular protein glutathione peroxidase-gastrointestinal comprising administration of selenium or selenium salts.

Group X, claim(s) 42-43, 46-50 (all in part), drawn to a method for regulating the expression or activity of the human cellular protein glutathione peroxidase-gastrointestinal comprising administration of Vitamin D3.

Group XI, claim(s) 42-43, 46-50 (all in part), drawn to a method for regulating the expression or activity of the human cellular protein glutathione peroxidase-gastrointestinal comprising administration of all trans retinoic acid, a derivative thereof or 4-HPR.

Group XII, claim(s) 42-43, 46-50 (all in part), drawn to a method for regulating the expression or activity of the human cellular protein glutathione peroxidase-gastrointestinal comprising administration of a naphthalene derivative TTNPB, AM-580 or AHPN.

3. The inventions listed as Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Groups I-IV (or V-VIII or IX-XII) lack a corresponding technical feature a priori. Each of the groups of compounds are completely different, with different chemical backbone structures. Groups I (or II-IV), V (or VI-VIII) and IX (or X-XII) are linked by the technical feature of an agent of the group.

Bankit, et al. (US 4,668,515) teaches compositions containing sodium selenite (claim 4) which are fed to a mammal (abstract; throughout), with concentration ranges that overlap the instant disclosure (i.e., these compositions would be useful for the purposes of the instant claims). Since Bankit previously disclosed compositions of the instant claims the technical feature is lacking novelty.

Therefore the technical feature linking the inventions of Groups I-XII does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art. Accordingly, Groups I-XII are not so linked by the same or a corresponding special technical feature as to form a single inventive concept.

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

For any group elected, applicant is required to elect (i) or (ii) or (iii) and specify the corresponding specie(s), as designated:

(i) a composition or the administration of a composition comprised of a single active agent (claim 1, 9, 42) (if elected applicant is also required to specify a single disclosed active agent compound specie from the species in claims 1, 9, 42); or

(ii) a composition comprised of more than one active agent; at least one agent from the species in claims 1, 9 or 42, and at least one from the species in claims 5, 6, 13, 14, 50 (claims 5, 6, 13, 14, 50) (if elected specify a single disclosed

compound specie for each active agent of the composition; at least one from the species in claims 1, 9 or 42, and at least one from the species in claims 5, 6, 13, 14, 50); or

(iii) any other combination of active agents not specified in (ii) (if elected, specify a single disclosed active agent specie for each active agent of the composition).

If any of Groups VI-XII is elected, applicant is also required to elect:

(iv) a method, where the method occurs in

(iva) an individual (in vivo) (claims 9, 42, 47); or

(ivb) cells or cell cultures (in vitro) (claims 23, 46, 49).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. The claims are deemed to correspond to the species listed above in the following manner:

(i) Claims 1-4, 7-12, 15-20, 23, 27-35, 42-43 and 46-49, 51-56

(ii) Claims 1-20, 23, 27-35, 42-43 and 46-56

(iii) Claims 1-4, 7-12, 15-20, 23, 27-35, 42-43 and 46-49, 51-56

(iv) Claims 9-12, 15-18, 23, 27-35, 42-43 and 46-49, 51-56

The following claim(s) are generic: Claims 1-4, 7-12, 15-20, 23, 27-35, 42-43 and 46-49, 51-56 are generic to (i) and (ii).

6. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: As outlined above, the species have been taught in the prior art; therefore the technical feature linking the species lacks novelty, the technical featured does not comprise a special technical feature and no single inventive concept links the species.

7. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the

record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy P. Thomas whose telephone number is (571) 272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/TPT/
Timothy P. Thomas
Patent Examiner

Ardin H. Marschel 9/10/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER